

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON TALCUM
POWDER PRODUCTS MARKETING,
SALES PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-
2738-FLW-LHG**

MDL No. 2738

***THIS DOCUMENT RELATES TO ALL
CASES***

**THE PLAINTIFFS' STEERING COMMITTEE'S REPLY MEMORANDUM
OF LAW IN SUPPORT OF THE MOTION TO EXCLUDE THE OPINIONS
AND TESTIMONY OF DEFENDANTS' GYNECOLOGY-ONCOLOGY
EXPERTS DR. CHERYL SAENZ AND DR. KEVIN HOLCOMB**

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The Plaintiffs' Steering Committee ("PSC") respectfully submits this reply memorandum in support of its motion to exclude the opinions and testimony of Defendants Johnson & Johnson and Johnson & Johnson Consumer, Inc.'s (together, "J&J") gynecologic ("GYN") oncology experts Dr. Cheryl Saenz And Dr. Kevin Holcomb.¹

I. INTRODUCTION

While J&J's GYN oncologists Dr. Holcomb and Dr. Saenz are generally qualified as GYN oncologists, their general causation opinions in this case are lacking the requisite support and reliability. J&J offers very little to defend them. J&J is forced to cite its own briefing and experts rather than evidence, and largely ignores and mischaracterizes Drs. Holcomb and Saenz's actual stated opinions and testimony. But it is the experts' opinions and stated bases for those opinions that matter under *Daubert*, not the words of counsel.

The following opinions of Drs. Holcomb and Saenz must be excluded:

¹ *The Plaintiffs' Steering Committee's Memorandum of Law in Support of its Motion to Exclude the Opinions and Testimony of Defendants Gynecology-Oncology Experts Dr. Cheryl Saenz and Dr. Kevin Holcomb*, ECF No. 9735-1, is referred to herein as "PSC Brief at ____."

- the epidemiology does not demonstrate a causal connection because the cohort studies do not show an association;²
- the epidemiology does not demonstrate a causal connection because the case control studies are negated by recall bias, a lack of statistical significance, and a “weak association”;³
- migration does not occur because there is not a study proving that talcum powder applied to the perineum travels to the ovaries;⁴
- the PSC’s experts’ opinions on biological plausibility are not supported by the evidence;⁵ and
- Dr. Smith-Bindman committed reporting errors in her analysis of the epidemiology.

These conclusions and opinions have been reached by J&J’s experts without them considering the data as a whole and through application of unsound methodology. These conclusions lack a sufficiently reliable foundation to be admissible under Rule 702.

A key fact in this case is that the meta-analyses and case-control studies are consistent and show statistically significant results. But, J&J’s experts do not appropriately consider this information. Instead, J&J’s experts essentially ignore the meta-analyses and case-control studies while automatically elevating the results of

² Holcomb Report (Exhibit D) at 8-9, 20; Saenz Report (Exhibit B) at 8, 15-16. All “Exhibit” references are to the Certification of P. Leigh O’Dell, Esq. [ECF No. 9735-4] filed in support of the PSC’s Motion, unless otherwise stated.

³ Holcomb Report at 8-9, 20; Saenz Report at 8-10, 12-13.

⁴ Holcomb Report at 16-17, 21; Saenz Report at 17-18, 20.

⁵ Holcomb Report at 21-22; Saenz Report at 20, 27-30.

cohort studies as being more or even most important. J&J attempts to downplay the infirmity in their experts' methodology by pointing out that Drs. Holcomb and Saenz at least discuss the meta-analyses and case-control studies in their reports. But, J&J ignores both experts' ultimate conclusions where they automatically elevate the cohort studies and their results above the consistent and statistically significant results of the meta-analyses and case-control studies. Mere recitation of the evidence is not enough. Drs. Holcomb and Saenz were required to actually consider the epidemiology in its totality. Because both failed to do so, their opinions should be excluded.

Additionally, while J&J's *counsel* argues Drs. Holcomb and Saenz's opinions on migration are based on "a wide variety of studies and other evidence" and not an improper standard of biological plausibility, both experts' actual testimony is to the contrary.⁶ Drs. Holcomb and Saenz reject migration as a plausible mechanism simply because there is not a precise study "proving" it.⁷ Biological plausibility does not require this level of proof and Drs. Holcomb and Saenz's opinions suggesting otherwise are unreliable and not helpful to the jury.

⁶ Def. Opp. at 30.

⁷ Holcomb Dep. at 129:24-130:4, 425:13-426:1 (attached as Exhibit C); Holcomb Report at 22; Saenz Report at 8; Saenz Dep. at 208:16-25 (Exhibit A).

Drs. Holcomb and Saenz also cannot opine that the PSC's experts' biological plausibility opinions are unsupported if neither has reviewed the evidence relied on by the PSC's experts. J&J admits that Drs. Holcomb and Saenz did not review and consider multiple important studies on biological plausibility cited to and discussed in the PSC's expert reports.⁸ Drs. Holcomb and Saenz cannot opine there is an absence of evidence if they have not reviewed the totality of the evidence, including evidence which may support an alternate conclusion.⁹ How can an expert state there is an "absence of evidence" when the expert does not even consider all of the evidence?

Finally, while Dr. Saenz is qualified to generally discuss the epidemiology in the context of her medical opinion, she has not demonstrated that her opinions criticizing Dr. Smith-Bindman's alleged reporting errors are supported by the evidence. Dr. Smith-Bindman is a well-qualified epidemiologist and any critique of her methodology should come from similarly qualified experts.

⁸ Def. Opp. at 33-34.

⁹ See *Innis Arden Golf Club v. Pitney Bowes, Inc.*, 629 F. Supp. 2d 175, 189 (D. Conn. 2009) (excluding expert testimony where expert failed to review evidence that may have supported an alternative explanation).

II. DRS. HOLCOMB AND SAENZ DO NOT FOLLOW AN ACCEPTED METHODOLOGY

A. Drs. Holcomb and Saenz Blindly Value the Cohort Studies Above All Other Epidemiology

Experts must base their opinions on the totality of the evidence and cannot selectively ignore contrary scientific literature.¹⁰ The reliability and admissibility of an expert's opinion must be questioned where, as here, the experts form their opinions and then backfill those opinions with cherry-picked evidence.¹¹ That is precisely what Drs. Holcomb and Saenz did. They automatically valued cohort studies above all other epidemiological evidence because they view the cohort studies as not showing a statistically significant association.

J&J points to discussion of the meta-analyses and case-control studies in Dr. Holcomb and Dr. Saenz's reports as proof that Holcomb and Saenz must have considered them. But J&J ignores both experts' actual conclusions. While they reference the other epidemiology, Drs. Holcomb and Saenz conclude that there is no association because the cohort studies are "more credible" than case-control studies and meta-analyses and "[n]one of the cohort studies demonstrates a statistically

¹⁰ *In re Neurontin Mktg. & Sales Practices Litig.*, 04-cv-10739-PBS, 2011 WL 3852254, at *34 (D. Mass. Aug. 31, 2011), *aff'd*, 712 F.3d 21 (1st Cir. 2013); *In re Zolof (Sertraline Hydrochloride) Prod. Liab. Litig.*, 26 F. Supp. 3d 449, 461 (E.D. Pa. 2014).

¹¹ *In re Seroquel Prods. Liab. Litig.*, 6:06-md-1769-ORL-22D, 2009 WL 3806434, at *5 (M.D. Fla. June 18, 2009); *In re Zolof*, 26 F. Supp. 3d at 461.

significant association between talc and ovarian cancer.”¹² Relying on some stated hierarchy of evidence without evaluation of the actual strengths and weaknesses of the individual studies is improper.¹³

J&J glosses over Dr. Holcomb’s bizarre citation to a hierarchy he found on a business management website, claiming that Dr. Holcomb “was not relying on the graphic to inform his opinion.”¹⁴ But Dr. Holcomb not only cites to the hierarchy,

¹² Saenz Report at 8; Holcomb Report at 9 (concluding no association because “no prospective cohort study with long-term follow up has shown an increased risk of ovarian cancer associated with cosmetic talc use”); *see also Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.’s Memorandum of Law in Opposition to Plaintiffs’ Steering Committee’s Motion to Exclude the Opinions and Testimony of Defendants’ Experts Dr. Cheryl Saenz and Dr. Kevin Holcomb*, ECF No. 9877, (“Defs. Opp.”) at 5.

¹³ *See Plaintiffs’ Steering Committee’s Omnibus Memorandum of Law in Response and Opposition to Defendants’ Johnson & Johnson and Johnson & Johnson Consumer, Inc.’s Motion to Exclude Plaintiffs’ General Causation Opinions*, ECF No. 9888, (“PSC Gen. Caus. Opp.”) at 127-131 (citing Kenneth J. Rothman, *Six Persistent Research Misconceptions*, 29 J. Gen. Internal Med. 1060, at p. 1061 (2014) (“[D]iscrepancies between cohort studies and case control studies should not be explained away superficially by a presumed advantage of cohort studies over case-control studies.”); Kenneth J. Rothman, et al. *Interpretation of Epidemiologic Studies on Talc and Ovarian Cancer* at 3 (Nov. 28, 2000) (“It is commonly believed that the validity of case-control studies is worse than cohort studies, but this view is mistaken. The validity of a study depends on the specifics of the study design, that nature of the data, and the nature of the hypothesis that the study addresses.”); Leon Gordis, *Epidemiology* at 245, 257 (5th ed. 2013)); *see also The Plaintiffs’ Steering Committee’s Memorandum of Law in Reply to Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.’s Memorandum of Law in Opposition to Plaintiffs’ Motion to Exclude the Opinions of Defendants’ Epidemiology Experts* (“PSC Epi. Reply”), being filed concurrently.

¹⁴ Defs. Opp. at 10.

he reproduces it in his report and critiques the PSC's experts for not relying on it.¹⁵

Dr. Holcomb testified that he picked this hierarchy because it fit his opinions "best."¹⁶ Even Dr. Karla Ballman, another J&J expert who created her own hierarchy chart, concedes that meta-analyses are a higher quality study than both cohort and case-control studies and should be considered.¹⁷ Blindly placing more weight on the cohort studies based solely on a hierarchy of evidence without actual consideration of the individual studies is improper.

J&J and its experts' discussion of the cohort studies also is misleading. Gertig 2008 found a 40% statistically significant increased risk with serous epithelial ovarian cancer,¹⁸ and when combined in a meta-analysis, the cohort studies together

¹⁵ Holcomb Report at 8.

¹⁶ Holcomb Dep. at 281:21-282:6.

¹⁷ February 25, 2019 Expert Report of Karla Ballman, Ph.D. for General Causation Daubert Briefing ("Ballman Report") at 4, n.1 (recognizing that "[a] meta-analysis of observational data falls below that of individual clinical trials" and above cohort studies). Notably, Dr. Ballman's self-created hierarchy is not published or peer-reviewed. Meta-analyses are considered "the quantitative backbone of the evidence-based medicine program." Brewster, W., "Epidemiology of Commonly Used Statistical Terms and Analysis of Clinical Studies," *Clinical Gynecology Oncology* (9th ed. 2017) (attached hereto as Exhibit 1).

¹⁸ Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*, 92 J. Nat'l Cancer Inst. 249, at p. 250 (2000) (finding 40% increase for serous) (attached hereto as Exhibit 2).

demonstrated a 25% statistically significant increased risk for serous ovarian cancer.¹⁹ Drs. Holcomb and Saenz ignore this data.

Drs. Holcomb and Saenz attempt to justify their minimization of the importance of the meta-analyses and case-control studies by attributing the results of those studies to recall bias. But J&J cannot defend Drs. Holcomb and Saenz's conclusions as their analysis of recall bias was entirely deficient. Pointing to deposition testimony, J&J contends that both experts relied on more than just Schildkraut 2016 to dismiss the case-control studies on the basis of recall bias. J&J cites to Dr. Holcomb's claim that he observed "[a] trend in the strength of association also increasing over time," which would suggest that widespread media coverage of the talcum powder litigation artificially increased the odds ratios over time.²⁰ But J&J failed to read on in Dr. Holcomb's deposition. When pressed to look at the data, Dr. Holcomb admitted that the odds ratios in fact did not increase over time, thereby undermining the argument that media coverage has skewed the strength of association through recall bias.²¹

¹⁹ Penninkilampi et al., *Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis*, 29 *Epidemiology* 41, at p. 44 (2018) (finding 25% increased risk of serous invasive from cohort studies) (Exhibit I).

²⁰ Def. Opp. at 20 n.78 (citing Holcomb Dep. at 268:9-15).

²¹ Holcomb Dep. at 269:12-270:13.

J&J's citation to Dr. Saenz's testimony also does not support dismissal of the case-control studies based on recall bias. Dr. Saenz testified that the only other data she considered besides Schildkraut 2016 regarding recall bias was Penninkilampi.²² However, Penninkilampi concluded that "[w]hile the results of case-control studies are prone to recall bias, especially with intense media attention following the commencement of litigation in 2014, the confirmation of an association in cohort studies between perineal talc use and serous ovarian cancer is suggestive of a causal association."²³ Rather than attempt to reconcile these study results with the totality of the data, Drs. Holcomb and Saenz ignored the positive results from the cohort studies and this conclusion by Penninkilampi. Drs. Holcomb and Saenz's dismissal of the case-control studies as being affected by recall bias, without any actual analysis, is unreliable and should be excluded.

J&J also misconstrues the PSC's arguments on strength of association. The PSC does not argue that an association in the range of 1.2 to 1.6 is strong.²⁴ Rather, the PSC argues that it is improper for Dr. Saenz to dismiss the statistically significant results of the case-control studies simply based on a description of them in isolation as being "weak" or "modest" because they are below 2.0. Dr. Saenz was required to

²² Defs. Opp. at 20, n.75 (citing Saenz Dep. at 305:5-12).

²³ Penninkilampi et al. (2018) at p. 47.

²⁴ Defs. Opp. at 23. *See also* PSC Gen. Caus. Opp. at 134-139.

consider the actual risk estimates with the totality of the evidence.²⁵ She did not do that. Instead, she rejected the case-control studies' results because "[n]one of the studies demonstrated an odds ratio of >2 when looking at never/ever perineal use of talc and ovarian cancer."²⁶ That is an improper methodology.

Finally, J&J attempts to recraft the PSC's argument on statistical significance. The PSC does not argue that statistical significance should be ignored or that positive associations are only relevant if there is statistical significance.²⁷ To the contrary, the PSC contends that Dr. Holcomb was required to consider all the evidence that demonstrates an increased risk, while taking into account whether the results are statistically significant or not. To ignore certain studies demonstrating positive associations simply because the results did rise to the level of statistical significance is improper in the context of the evidence as a whole. That data must be considered

²⁵ PSC Gen. Caus. Opp. at 132-133 (quoting *Reference Manual* at 611, n. 186 ("While strength is a guideline for drawing an inference on causation from association...there is no specified threshold required."), and Rothman et al., *Modern Epidemiology* at 26 ("[A] strong association is neither necessary nor sufficient for causality, and [] weakness is neither necessary nor sufficient for absence of causality.")).

²⁶ Saenz Report at 9.

²⁷ Defs. Opp. at 27.

with the totality of the evidence, including the numerous studies that did show a statistically significant positive association.²⁸

B. Drs. Holcomb and Saenz’s Biological Plausibility Opinions Are Based on an Incorrect Standard

J&J also attempts to rewrite Drs. Holcomb and Saenz’s opinions on biological plausibility. According to J&J, Drs. Holcomb and Saenz only opine that “some ‘evidence’ of a mechanism” is required.²⁹ That is not what Drs. Holcomb and Saenz testified to in arriving at their opinions.

Drs. Holcomb and Saenz clearly opine that without an exact study proving talcum powder applied to the perineum migrates to the ovaries, migration does not occur.³⁰ The PSC is not tasked with that level of proof.³¹ Drs. Holcomb and Saenz’s opinions on biological plausibility are misplaced and confuse biological plausibility

²⁸ Amrhein, Greenland & McShane, *Retire Statistical Significance*, 567 *Nature* 305 (2019) (attached hereto as Exhibit 3); PSC Brief at 17.

²⁹ Defs. Opp. at 31.

³⁰ Holcomb Dep. at 129:24-130:4 (“What I’m saying is the study they should look at would be the study where someone dusted the human perineum with talc and showed that it was able to reach the ovary, and that doesn’t exist.”); *see also* Holcomb Dep. at 425:13-426:1 (disagreeing with the FDA’s conclusion that migration is indisputable because “there’s no studies showing that perineal talc can make it to the ovaries”); Holcomb Report at 22 (criticizing Dr. Clarke-Pearson because “none of the articles he cited actually looked at whether talc can migrate from the perineal application through the fallopian tubes to the ovaries”); Saenz Report at 8 (“There is not a single study demonstrating such migration from the perineum to the ovaries.”); Saenz Dep. at 208:16-25.

³¹ PSC Brief at 25.

with the concept of “proof.” Biological plausibility is not the same as biological proof or certainty.³² Neither science nor *Daubert* require proof of mechanism. The PSC’s experts are “not required to show that a mechanism has been definitely established. Instead, [they] just need [] to show that the methodology [they] used to arrive at [their] opinions is sufficiently reliable.”³³ J&J’s experts however, are requiring “proof” of biological plausibility, based on a standard that is above what is required. These opinions should be excluded.

Additionally, because Drs. Holcomb and Saenz pre-determined that biological plausibility does not exist in the absence of an exact study proving it, they concede that they chose to dispense with the need to apply acceptable methodological processes which would require them to analyze the totality of the relevant studies considered and relied on.³⁴

It is certainly true that, in general, an expert may be able to provide an opinion based on review of data without reviewing every possible study on the subject. However, that is not what Drs. Holcomb and Saenz do. Rather, they opine that the

³² *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1308 (N.D. Fla. 2018).

³³ *In re Fosamax Prods. Liab. Litig.*, No. 11-5304, 2013 WL 1558697, at *6 (D.N.J. Apr. 10, 2013) (citing *Milward v. Acuity Specialty Prods. Group*, 639 F.3d 11, 15 (1st Cir. 2011)).

³⁴ Defs. Opp. at 34 (conceding that Drs. Holcomb and Saenz did not review several important studies on biological plausibility relied on by the PSC’s experts).

PSC's experts' biological plausibility opinions are not supported by the evidence.³⁵

Query, how can Drs. Holcomb and Saenz conclude that there is no evidence supporting the PSC's experts' opinions if Drs. Holcomb and Saenz did not bother to consider the evidence relied upon by the PSC's experts?³⁶ *They cannot.*

The studies they failed to consider clearly support a plausible mechanism. For example, Buz'Zard and Lau 2007 demonstrated through *in vitro* data that "talc may contribute to ovarian carcinogenesis in humans by way of inducing aberrant ROS [reactive oxygen species] generation" and Shukla 2009 demonstrated that both asbestos and fibrous talc caused inflammation in exposed mesothelial cells.³⁷

³⁵ Saenz Report at 27 ("Plaintiffs' experts' hypotheses of biologic plausibility are pure speculation."); Holcomb Report at 22 (concluding that "[t]he studies that plaintiffs' experts did address also do not confirm their hypothesis.").

³⁶ *Water Pollution Control Auth. of Norwalk v. Flowserve US Inc.*, No. 3:14-cv-00549 (VLB), 2018 U.S. Dist. LEXIS 52168, at *48 (D. Conn. Mar. 28, 2018) (an opinion that is not based on "all relevant facts and data" is not sufficiently reliable); *In re Neurontin*, 2011 WL 3852254, at *34; *In re Zolofit*, 26 F. Supp. 3d at 461. Indeed, based on the literature, J&J's own expert Dr. Birrer previously agreed, contrary to Drs. Holcomb and Saenz and J&J's counsel, that "[a]ny material – whether it be talc, heavy metals, asbestos, whatever – can migrate from the perineum to the ovaries through the reproductive tract. There's an anatomical conduit." *The Plaintiffs' Steering Committee's Memorandum of Law in Response and Opposition to Defendants Johnson & Johnson and Johnson & Johnson Consumer, Inc.'s Motion to Exclude Plaintiffs' Experts' Opinions Related to Biological Plausibility* [ECF No. 9890] at 16 (quoting September 25, 2018 Deposition of Michael Birrer, M.D., *Brower, et al. v. Johnson & Johnson, Inc. et al.*, at 96:22-97:8).

³⁷ Buz'Zard and Lau, *Pycnogenol Reduces Talc-Induced Neoplastic Transformation in Human Ovarian Cell Cultures*, *Phytother Res*, 21:579-586, at p. 586 (2007); Shukla et al., *Alterations in Gene Expression in Human Mesothelial Cells Correlate with Mineral Pathogenicity*, *Am J Respir Cell Mol Biol*, 41:114-123, at p. 121

Without consideration of the totality of the evidence relied on by the PSC's experts, Drs. Holcomb and Saenz's opinions are conclusion driven rather than based on the evidence and should be excluded.

C. Dr. Saenz's Opinion On Dr. Smith-Bindman's Alleged Reporting Errors Is Unsupported

Finally, while Dr. Saenz may generally comment on the relevant epidemiology in the context of her medical opinions as a GYN oncologist, her opinions regarding alleged reporting errors by the PSC's epidemiologist Dr. Smith-Bindman are unsupported and reveal a misunderstanding of Dr. Smith-Bindman's analysis. These opinions are not helpful to the jury.

Dr. Smith-Bindman clearly stated that her analysis focused on daily use, or as close to it as possible.³⁸ J&J's suggestion that Dr. Saenz "could not have been

(2009). Dr. Holcomb opines that while talc causes inflammation, its use in pleurodesis treatment confirms it does not cause cancer. Defs. Opp. at 9 (citing Holcomb Report at 18-19). However, the reason cancer is not linked to pleurodesis treatment is because patients undergoing pleurodesis usually already have advanced cancer with a "[m]edian survival following diagnosis rang[ing] from 3 to 12 months...." Roberts et al., *Management of a malignant pleural effusion: British Thoracic Society pleural disease guideline 2010*, Thorax, 65:ii32-ii40, at p. ii32 (2010) (attached hereto as Exhibit 4); March 29, 2019 Deposition of Michael Birrer, M.D., Ph.D. at 295:9-293:13 (attached hereto as Exhibit 5) (testifying that he is not concerned about using talc for pleurodesis because those patients are "cancer patients, in which case, unfortunately, longevity makes this whole issue moot").

³⁸ See PSC Brief at 34 (citing Feb. 7, 2019 Deposition of Rebecca Smith-Bindman, M.D. at 149:17-150:1).

expected to know” this is nonsense.³⁹ J&J deposed Dr. Smith-Bindman on February 2, 2019, where she explained her analyses in detail. Dr. Saenz’s expert report dated February 25, 2019, where she attempts to critique Dr. Smith-Bindman should have taken into account Dr. Smith-Bindman’s full opinions and testimony. Dr. Saenz did not do that. Dr. Smith-Bindman is a well-qualified epidemiologist and any critique of her opinions should be left to other qualified epidemiologists who have considered the entire record.

III. CONCLUSION

For the foregoing reasons, the PSC’s motion to exclude the opinions of Dr. Kevin Holcomb and Dr. Cheryl Saenz should be granted in its entirety.

Respectfully submitted,

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³⁹ Defs. Opp. at 41 (arguing that “Dr. Saenz could not have been expected to know that”).

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